

### **REMARKS**

The claims have been amended in order to more completely describe and distinctly claim the invention and to overcome the various grounds of rejection set forth in the Official Letter.

The Examiner stated in the previous Office action that the previous claims had been renumbered as claims 13-25; however, this does not appear to be accurate. The application was originally filed with 13 original claims. The first Official Letter only acknowledged the presence of 12 claims and required election as between composition claims and method claims. Applicant elected the composition invention defined by claims 1 and 4-12, also inadvertently ignoring the presence of claim 13. The present amendment seeks to correct the matter by canceling all of the claims previously present in the application, whether numbered as 13 or 14-25 and replacing them with new claims 26-31. New claim 26 corresponds to previous claim 14 (renumbered by the Examiner as claim 13) which incorporates the limitations of previous claim 23 (renumbered by the Examiner as claim 21). New claim 27 corresponds to previous claim 17 (renumbered by the Examiner as claim 16). New claim 28 corresponds to previous claim 18 (renumbered by the Examiner as claim 17). New claim 29 corresponds to previous claim 20 (renumbered by the Examiner as claim 18). New claim 30 corresponds to previous claim 21 (renumbered by the Examiner as claim 19). New claim 31 corresponds to previous claim 24 (renumbered by the Examiner as claim 22). Inasmuch as no new matter is embodied by the proposed amendments, entry thereof is respectfully requested.

In addition, inasmuch as the new claims present no new issues not heretofore considered by the Examiner, their entry, although presented after final rejection, is respectfully requested.

The Examiner's objections to the claims set forth in the first paragraph of page 2 are believed to be overcome by the above amendments whereby the claims are now appropriately numbered. Accordingly, withdrawal of these grounds of objection is respectfully requested.

Referring to the second paragraph of page 2, all claims directed to non-elected subject matter have been cancelled.

The rejection of the claims under 35 USC 112 is believed to be obviated by the above amendment, whereby the alternativeness of the previous claims has been eliminated. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 USC 102 over Panoz as being completely anticipated is respectfully traversed insofar as this ground of rejection is directed to the claims as presently amended.

The passages of Panoz being particularly applied by the Examiner (col. 3, lines 66-68 and col. 4, lines 1-2) disclose an ointment containing nitroglycerine and lactose in lanolin and white petrolatum base for transdermal administration of the active ingredient in order to provide a sustained release thereof from a laminar applicator such a layer of aluminum foil which overlies the skin, the particular objective being to ensure that the active ingredient is transferred unidirectionally to the skin rather than to the material of the applicator. Nitroglycerine in particular is prone to migration through the applicator, especially when formed from a paper material, and to escape into the atmosphere. As far as I can understand the teaching of Panoz, the unidirectional transdermal administration of the drug is more a function of the structure of the applicator rather than of the formulation but the formulation, whether applied from an applicator or, presumably but not described, direct to the skin as a topical ointment, is intended to provide controlled release of the active ingredient (column 5,

line 15) whereby the ointment can be applied once a day rather than in eight-hourly application periods (column 5, lines 56-59).

The Examiner, on page 4, indicates that a recitation of intended use must result in a structural difference between the claimed invention and the prior art and that, if the prior art structure is capable of performing the intended use, then it meets the claim. However, the prior art as represented by Panoz, is unsuitable for use in the present invention. In the first place, an applicator of the type described is unsuitable for attachment to the skin of the penis and in the second place, even without an applicator, the ointment itself would appear to be unsuitable because sustained release of the active ingredient is not what is required for treatment of erectile dysfunction or cosmetic effect.

The inventive composition also includes water. In Panoz, the lanolin and white petrolatum ingredients are said to constitute a “special absorptive base formulated to provide a controlled release of the active ingredient”. One can only understand from this that the absence of water is significant for this purpose and it follows that the presence of water could be regarded as a “structural difference” sufficient to distinguish the present invention from the prior art.

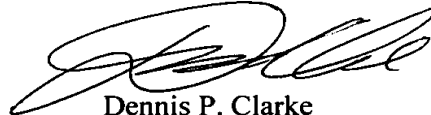
In any event, Panoz does not disclose a composition containing water, nor does the reference suggest such a presence.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Applicants have earnestly endeavored to place this application in condition for allowance and an early action to that end is respectfully requested.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Dennis P. Clarke', is written over the printed name.

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